- 1 CABINET FOR HEALTH AND FAMILY SERVICES
- 2 Department for Medicaid Services
- 3 Division of Policy and Provider Operations
- 4 (Amendment)
- 5 907 KAR 1:180. <u>Freestanding[Alternative]</u> birth center services.
- 6 RELATES TO: KRS 205.520
- 7 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 42 C.F.R.
- 8 440.170, 42 U.S.C. 1396a, b, d[, EO 2004-726]
- 9 NECESSITY, FUNCTION, AND CONFORMITY: [EO 2004-726, effective July 9, 2004,
- 10 reorganized the Cabinet for Health Services and placed the Department for Medicaid
- Services and the Medicaid Program under the Cabinet for Health and Family Services.
- 12 The Cabinet for Health and Family Services has responsibility to administer the program
- of Medical Assistance. KRS 205.520(3) empowers the cabinet, by administrative regula-
- tion, to comply with any requirement that may be imposed, or opportunity presented, by
- 15 federal law to qualify for federal Medicaid funds[for the provision of medical assistance to
- 16 Kentucky's indigent citizenry]. This administrative regulation establishes[sets forth] the
- coverage provisions for services provided by <u>freestanding[alternative]</u> birth centers for
- which payment shall be made by the Medicaid Program in behalf of both the categorically
- 19 needy and the medically needy.
- Section 1. Definitions. (1) "Advanced practice registered nurse" is defined by KRS
- 21 **314.011(7)**.

- 1 (2) "Department" means the Department for Medicaid Services or its designee.
- 2 (3) "Enrollee" means a recipient who is enrolled with a managed care organization.
- 3 (4) "Freestanding birth center" means a:
- 4 (a) Freestanding birth center as defined by 42 USC 1396d(I)(3)(B); and
- 5 (b) Facility that is licensed as an alternative birth center in accordance with 902 KAR
- 6 **20:150**.
- 7 (5) "Freestanding birth center services" is defined by 42 USC 1396d(28) and 42 USC
- 8 <u>1396d(l)(3)(A).</u>
- 9 (6) "Managed care organization" means an entity for which the Department for Medi-
- caid Services has contracted to serve as a managed care organization as defined in 42
- 11 **C.F.R. 438.2.**
- (7) "Participating freestanding birth center" means a freestanding birth center that is:
- (a) Currently enrolled in the Medicaid program pursuant to 907 KAR 1:672;
- (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671;
- (c) Licensed in accordance with 902 KAR 20:150; and
- (d) Authorized to provide the service in accordance with this administrative regula-
- 17 **tion.**
- 18 (8) "Provider" is defined by KRS 205.8451(7).
- (9) "Recipient" is defined by KRS 205.8451(9).
- 20 (10) "Rendering provider" means a provider who:
- (a) Provides a service for which reimbursement is:
- 22 <u>1. Made to the provider; and</u>
- 23 2. Not made to a freestanding birth center; and

- 1 **(b) ls**:
- 2 <u>1. A physician who provides a service associated with a freestanding birth center;</u>
- 2. A physician assistant who provides a service associated with a freestanding birth
- 4 center;
- 5 3. An advanced practice registered nurse who provides a service associated with a
- 6 freestanding birth center; or
- 7 <u>4. A registered nurse who provides a service associated with a freestanding birth cen-</u>
- 8 <u>ter.</u>
- 9 (11) "Registered nurse" is defined by KRS 314.011(5).
- Section 2. General Provisions and Requirements. (1) For the department to reimburse
- for a freestanding birth center service, the service shall:
- 12 (a) Be provided:
- 13 1. To a recipient; and
- 14 **2. By a:**
- a. Participating freestanding birth center that is currently licensed and operating in
- accordance with 902 KAR 20:150; or
- b. Rendering provider;
- (b) Be covered in accordance with this administrative regulation; and
- 19 (c) Be medically necessary.
- (2)(a) A participating freestanding birth center shall comply with:
- 21 <u>1. 907 KAR 1:671;</u>
- 22 **2. 907 KAR 1:672**;
- 23 3. 902 KAR 20:150; and

- 4. All applicable state and federal laws.
- 2 (b) A rendering provider shall comply with:
- 3 <u>1. 907 KAR 1:671;</u>
- 4 <u>2. 907 KAR 1:672; and</u>
- 5 <u>3. All applicable state and federal laws.</u>
- 6 (3)(a) If a participating freestanding birth center or rendering provider receives any
- 7 <u>duplicate payment or overpayment from the department, regardless of reason, the</u>
- 8 participating freestanding birth center or rendering provider shall return the payment to
- 9 the department.
- (b) Failure to return a payment to the department in accordance with paragraph (a) of
- this section may be:
- 1. Interpreted to be fraud or abuse; and
- 2. Prosecuted in accordance with applicable federal or state law.
- (c) Non-duplication of payments and third-party liability shall be in accordance with
- 15 **907 KAR 1:005**.
- (d)1. A freestanding birth center shall comply with KRS 205.622.
- 2. A rendering provider shall comply with KRS 205.622.
- 18 Section 3. Services shall be covered only when provided to an eligible Medicaid recipi-
- ent by a participating alternative birth center which is appropriately licensed and operating
- in accordance with 904 KAR 20:150.
- Section 2.] Covered Services. The following services may be provided by a freestand-
- ing[alternative] birth centers:
- (1) Prenatal visits, to include one (1) initial visit and follow-up visits as appropriate: [-]

- 1 (2) Standby services, with the rendering provider [medical professional (obstetrician or
- 2 nurse midwife)] physically present throughout the course of the labor;[-]
- 3 (3) Delivery including[, which includes] the actual delivery, necessary supplies and ma-
- 4 terial for the delivery, and the post-delivery[postdelivery] examination:[-]
- 5 (4) Postnatal visits:
- 6 (a) [,] Not to exceed two (2); and
- 7 (b) Which shall be accomplished within six (6) weeks of the delivery; or[-]
- 8 (5) Laboratory services <u>directly related to the provision of a freestanding birth center</u>
- 9 <u>service[as specified by the Cabinet for Health and Family Services].</u>
- Section <u>4.[3.]</u> Records, Reporting and Monitoring. <u>A freestanding birth center shall:</u>
- (1) Maintain complete and legible records of services provided and in a manner that
- ensures the confidentiality of the recipient of the service; and
- (2) Provide the records referenced in paragraph (a), upon request, to:
- 14 (a) The department;
- (b) The Cabinet for Health and Family Services Office of the Inspector General or its
- 16 designee;
- (c) The Office of the Auditor of Public Accounts or its designee;
- (d) The Office of the Attorney General or its designee;
- (e) The Centers for Medicare and Medicaid Services or its designee;
- (f) The Office of Inspector General of the United States Department of Health and Hu-
- 21 man Services or its designee; or
- (g) The United States Government Accountability Office or its designee.
- Section 5. Federal Financial Participation. A provision or requirement established in

- 1 this administrative regulation shall be null and void if the Centers for Medicare and Med-
- 2 icaid Services:
- 3 (1) Denies federal financial participation for the provision or requirement; or
- 4 (2) Disapproves the provision or requirement.
- 5 Section 6. Appeal Rights. (1) An appeal of a negative action regarding a Medicaid
- 6 <u>recipient who is:</u>
- 7 (1) Enrolled with a managed care organization shall be in accordance with 907 KAR
- 8 <u>17:010; or</u>
- 9 (2) Not enrolled with a managed care organization shall be in accordance with 907
- 10 KAR 1:563[The facility shall maintain complete records of services rendered, and provide
- to the cabinet the records and reports the cabinet requires for the effective implementa-
- tion and administration of the service. Facility records shall be available to the Cabinet for
- 13 Health and Family Services, the United States Department of Health and Human Ser-
- vices, and the Comptroller General, and their representatives or designees for auditing or
- 15 monitoring purposes

907 KAR 1:180	
REVIEWED:	
Date	Lawrence Kissner, Commissioner Department for Medicaid Services
APPROVED:	
Date	Audrey Tayse Haynes, Secretary Cabinet for Health and Family Services

907 KAR 1:180

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on September 23, 2013 at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by September 16, 2013 five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until September 30, 2013. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, <u>tricia.orme@ky.gov</u>, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601; Phone: (502) 564-7905; Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:180

Cabinet for Health and Family Services

Department for Medicaid Services

Agency Contact Person: Stuart Owen (502) 564-4321

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the Department for Medicaid Services' (DMS's) service and coverage provisions and requirements related to freestanding birth center services. Freestanding birth centers are authorized to provide delivery services for deliveries that are not complicated.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish DMS's service and coverage provisions and requirements related to freestanding birth center services. Covering freestanding birth centers is mandated by Section 2301 of the Affordable Care Act.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing DMS's service and coverage provisions and requirements related to freestanding birth center services.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing DMS's service and coverage provisions and requirements related to freestanding birthing center services.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The amendment inserts general provider requirements that were not previously stated in the administrative regulation; changes the facility's term from "alternative birthing center" to "freestanding birth center" to be consistent with language in the Affordable Care Act (and resulting federal law and regulation); establishes that policies are contingent upon receipt of federal funding/federal approval; and contains language or formatting changes to ensure compliance with KRS Chapter 13A standards (as the regulation has not been amended since 1992.)
 - (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to adopt the same term for these facilities as used in federal law and regulation and to insert general requirements that were not previously stated in the regulation.
 - (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by using language consistent with federal law and regulation and inserting general provider requirements such as program integrity or related requirements.

- (d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the authorizing statutes by using language consistent with federal law and regulation and inserting general provider requirements such as program integrity or related requirements.
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: Freestanding birth centers; physicians, advanced practice registered nurses, registered nurse, and physician assistants who would work for a freestanding birth center; and Medicaid recipients who would like to have a baby in a freestanding birth center as opposed to an inpatient hospital would be affected by the administrative regulation. DMS understands that currently there are no freestanding birth centers licensed or operating in Kentucky.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. No actions are required by the amendment.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed by the amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Freestanding birth centers and providers who provide services through the centers will benefit by being reimbursed for the services. Medicaid recipients will benefit by having an option to have a baby in a freestanding birth center rather than in an inpatient hospital. Freestanding birth centers provide a homelike setting for deliveries and perform deliveries in a manner that is less medically-oriented or rigid in protocol as inpatient hospitals. For example, freestanding birth centers typically do not induce or augment labor with oxytocin, do not provide continuous electronic fetal monitoring, do not provide epidural anesthesia, do not provide narcotics, and do not perform surgical deliveries.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
 - (a) Initially: The cost is indeterminable as currently, there are no freestanding birth centers operating in Kentucky. One (1) entity submitted an application for certificate of need (CON) in the autumn of 2012, a CON hearing was conducted in March 2013 and as of the filing of this administrative regulation, no decision had been made to grant or deny the certificate of need request. DMS understands that the applicant does not intend, if a CON is granted, to provide services to Medicaid recipients.
 - (b) On a continuing basis: The cost is indeterminable. Please see the above response to question (5)(a).

- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and matching state funds appropriated in the biennium budget.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement the amendment.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither imposes nor increases any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation Number: 907 KAR 1:180 Agency Contact Person: Stuart Owen (502) 564-4321

- 1. Federal statute or regulation constituting the federal mandate. Section 2301 of the Affordable Care Act which was codified into 42 USC 1396d(a)(28), 42 USC 1396d(l)(3), and 42 USC 1396a(a)(30)(A).
- 2. State compliance standards. KRS 194A.050(1) states, "The secretary shall promulgate, administer, and enforce those administrative regulations necessary to implement programs mandated by federal law, or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs."

KRS 205.520(3) states: " . . . it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

3. Minimum or uniform standards contained in the federal mandate.

42 U.S.C. 1396d(a)(28) establishes that medical assistance (Medicaid) includes "freestanding birth center services (as defined in subsection (I)(3)(A)) and other ambulatory services that are offered by a freestanding birth center (as defined in (I)(3)(B)) and that are otherwise included in the plan."

42 U.S.C. 1396d(I)(3) states:

- "(3)(A) The term freestanding birth center services means services furnished to an individual at a freestanding birth center (as defined in subparagraph (B)) at such center
- (B) The term freestanding birth center means a health facility
- (i) that is not a hospital;
- (ii) where childbirth is planned to occur away from the pregnant woman's residence;
- (iii) that is licensed or otherwise approved by the State to provide prenatal labor and delivery or postpartum care and other ambulatory services that are included in the plan; and
- (iv) that complies with such other requirements relating to the health and safety of individuals furnished services by the facility as the State shall establish.
- (C) A State shall provide separate payments to providers administering prenatal labor and delivery or postpartum care in a freestanding birth center (as defined in subparagraph (B)), such as nurse midwives and other providers of services such as birth attendants recognized under State law, as determined appropriate by the Secretary.

For purposes of the preceding sentence, the term birth attendant means an individual who is recognized or registered by the State involved to provide health care at child-birth and who provides such care within the scope of practice under which the individual is legally authorized to perform such care under State law (or the State regulatory mechanism provided by State law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. Nothing in this subparagraph shall be construed as changing State law requirements applicable to a birth attendant."

42 U.S.C. 1396a(a)(30)(A) requires Medicaid state plans to:

- ".... provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services"
- 4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No.
- 5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The requirements are not stricter than federal requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation Number: 907 KAR 1:180 Agency Contact Person: Stuart Owen (502) 564-4321

- What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be affected by this amendment.
- 2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This administrative regulation authorizes the action taken by this administrative regulation.
- 3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment will generate no revenue for DMS.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment will generate no revenue for DMS.
 - (c) How much will it cost to administer this program for the first year? The cost is indeterminable as currently, there are no freestanding birth centers operating in Kentucky. One (1) entity submitted an application for certificate of need (CON) in the autumn of 2012, a CON hearing was conducted in March 2013 and as of the filing of this administrative regulation, no decision had been made to grant or deny the certificate of need request. DMS understands that the applicant does not intend, if a CON is granted, to provide services to Medicaid recipients.
 - (d) How much will it cost to administer this program for subsequent years? The cost is indeterminable. Please see the above response in paragraph (c).

Note: If specific dollar estimates cannot be determined, provide a brief narrative explain the fiscal impact of the administrative regulation. Revenues (+/-):	∍ to
Expenditures (+/-): Other Explanation:	